

MEDICATION GUIDE
SOTYKTU™ (soh-tik-too)
(deucravacitinib)
tablets

What is the most important information I should know about SOTYKTU?

SOTYKTU may cause serious side effects, including:

- **Serious allergic reactions.** Stop taking SOTYKTU and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
 - feel faint
 - swelling of your face, eyelids, lips, mouth, tongue, or throat
 - trouble breathing or throat tightness
 - chest tightness
 - skin rash, hives
- **Infections.** SOTYKTU is a medicine that affects your immune system. SOTYKTU can lower the ability of your immune system to fight infections and can increase your risk of infections. Some people have had serious infections while taking SOTYKTU, such as infections of the lungs, including pneumonia and tuberculosis (TB), and COVID-19.
 - Your healthcare provider should check you for infections and TB before starting treatment with SOTYKTU.
 - Your healthcare provider may treat you for TB before you begin treatment with SOTYKTU if you have a history of TB or have active TB.
 - Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with SOTYKTU.
 - If you get a serious infection, your healthcare provider may tell you to stop taking SOTYKTU until your infection is controlled.

SOTYKTU should not be used in people with an active, serious infection, including localized infections. You should not start taking SOTYKTU if you have any kind of infection unless your healthcare provider tells you it is okay.

You may be at a higher risk of developing shingles (herpes zoster).

Before starting SOTYKTU, tell your healthcare provider if you:

- are being treated for an infection
- have had an infection that does not go away or keeps coming back
- have TB or have been in close contact with someone with TB
- have or have had hepatitis B or C
- think you have an infection or have symptoms of an infection such as:
 - fever, sweats, or chills
 - muscle aches
 - weight loss
 - cough
 - shortness of breath
 - blood in your phlegm (mucus)
 - warm, red, or painful skin or sores on your body different from your psoriasis
 - diarrhea or stomach pain
 - burning when you urinate or urinating more often than normal
 - feeling very tired

After you start taking SOTYKTU, call your healthcare provider right away if you have an infection or have symptoms of an infection.

SOTYKTU can make you more likely to get infections or make any infections you have worse.

- **Cancer.** Certain kinds of cancer including lymphoma have been reported in people taking SOTYKTU.
 - Tell your healthcare provider if you have ever had any type of cancer.
- **Muscle problems (rhabdomyolysis).** SOTYKTU can cause muscle problems that can be severe. Treatment with SOTYKTU may increase the level of an enzyme in your blood called creatine phosphokinase (CPK) and can be a sign of muscle damage. Increased CPK is common in people taking SOTYKTU. Your healthcare provider may tell you to stop taking SOTYKTU if the amount of CPK in your blood gets too high or if you have signs and symptoms of severe muscle problems. Tell your healthcare provider right away if you have any of these signs or symptoms of severe muscle problems:
 - unexplained muscle pain, tenderness, or weakness
 - feeling very tired
 - fever
 - dark-colored urine

See “**What are the possible side effects of SOTYKTU?**” for more information about side effects.

SOTYKTU™ (deucravacitinib)

What is SOTYKTU?

SOTYKTU is a prescription medicine used to treat adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).

It is not known if SOTYKTU is safe and effective in children under 18 years of age.

Do not take SOTYKTU if you are allergic to deucravacitinib or any of the ingredients in SOTYKTU. See the end of this Medication Guide for a complete list of ingredients in SOTYKTU.

Before taking SOTYKTU, tell your healthcare provider about all of your medical conditions, including if you:

- See “**What is the most important information I should know about SOTYKTU?**”
- have liver problems or kidney problems
- have high levels of fat in your blood (triglycerides)
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with SOTYKTU.
- are pregnant or plan to become pregnant. It is not known if SOTYKTU can harm your unborn baby.
 - Report pregnancies to the Bristol-Myers Squibb Company’s Adverse Event reporting line at 1-800-721-5072.
- are breastfeeding or plan to breastfeed. It is not known if SOTYKTU passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take SOTYKTU?

- Take SOTYKTU exactly as your healthcare provider tells you to take it.
- Take SOTYKTU 1 time every day.
- Take SOTYKTU with or without food.
- Do not crush, cut, or chew the SOTYKTU tablets.

What are the possible side effects of SOTYKTU?

SOTYKTU may cause serious side effects, including:

- See “**What is the most important information I should know about SOTYKTU?**”
- **Changes in certain laboratory test results.** Changes in laboratory tests have happened in some people taking SOTYKTU. Your healthcare provider may do blood tests before you start taking SOTYKTU and during treatment with SOTYKTU to check for the following:
 - **Increased triglycerides.** Triglycerides are a type of fat found in your blood. Too much fat in your blood can cause problems with your heart.
 - **Increased liver enzymes.** Liver enzymes are found in your blood and help to tell if your liver is functioning normally. If your liver enzymes increase too much, your healthcare provider may need to do additional tests on your liver and may tell you to stop taking SOTYKTU if they think that SOTYKTU is harming your liver.
- **Potential risks from Janus kinase (JAK) inhibition.** SOTYKTU is a tyrosine kinase 2 (TYK2) inhibitor. TYK2 is in the JAK family. It is not known whether taking SOTYKTU has the same risks as taking JAK inhibitors. Increased risk of death (all causes) has happened in people who were 50 years of age and older with at least 1 heart disease (cardiovascular) risk factor who were taking a JAK inhibitor used to treat rheumatoid arthritis (RA) compared to people taking another medicine in a class of medicines called TNF blockers. SOTYKTU is not for use in people with RA.

The most common side effects of SOTYKTU include:

- common cold, sore throat, and sinus infection (upper respiratory infections)
- cold sores (herpes simplex)
- sores on inner lips, gums, tongue, or roof of the mouth (canker sores)
- inflamed hair pores (folliculitis)
- acne

These are not all of the possible side effects of SOTYKTU.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SOTYKTU?

Store SOTYKTU at room temperature between 68°F to 77°F (20°C to 25°C).

Keep SOTYKTU and all medicines out of the reach of children.

SOTYKTU™ (deucravacitinib)

General information about the safe and effective use of SOTYKTU.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SOTYKTU for a condition for which it was not prescribed. Do not give SOTYKTU to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SOTYKTU that is written for health professionals.

What are the ingredients in SOTYKTU?

Active ingredient: deucravacitinib.

Inactive ingredients: anhydrous lactose, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose and silicon dioxide. In addition, the film coating Opadry® II Pink contains the following inactive ingredients: polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide red and yellow.

Distributed by:
Bristol-Myers Squibb Company
Princeton, New Jersey 08543 USA

For more product information about SOTYKTU, go to website (www.sotyktu.com) or call SOTYKTU 360 SUPPORT at 1.888.SOTYKTU (768.9588).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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